Remarks

Applicant has reviewed the Final Office Action mailed June 2, 2011. Claims 1-37 are pending prior to entry of this amendment. By this amendment, claims 1, 4-11, 14, 15, 19, and 25-33 are amended. Claims 17 and 33 are cancelled without prejudice or disclaimer of the subject matter therein, and new claims 38-46 are included. After entry of this amendment, claims 1-16, 18-32, and 34-46 will be pending in the application. Applicant respectfully submits the following remarks.

Claim Rejections Under 35 U.S.C. §§ 102, 103

Claims 1-7, 12-16 and 20-37 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,014,587, issued to Shaw et al. ("Shaw"). Claims 18-19 were rejected under §102(b) as being allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being allegedly obvious over Shaw. Claims 8-11, 17, 28-31 and 33 were rejected under § 103(a) as being allegedly obvious over Shaw.

Applicant respectfully traverses the rejections because Shaw does not disclose all the limitations of the claims. Although Applicant reserves the right to pursue the previously presented and originally filed claims in future prosecution, Applicant has amended the claims to further define the claimed invention, and more quickly advance the current prosecution toward allowable subject matter. To the extent the current rejections apply to the amended claims, Applicant respectfully submits that Shaw does not disclose or otherwise suggest all of the limitations of the claims as amended. In addition, Applicant respectfully submits that there is no convincing line of reasoning for a finding of obviousness in place of the undisclosed limitations.

Independent Claims

Independent claim 1 provides a method that includes operating a medical device system configured for treatment of a nervous system disorder producing one or more neurological events. The operation includes both a "manual mode" and a "run mode."[1] As discussed in Applicant's original Specification and now provided in claim 1, these modes of operation can be

[1] Claim 1 now incorporates limitations regarding operation in a run mode formerly provided in now-cancelled claim 17; claim 25 likewise incorporates limitations regarding operation in a run mode formerly provided in now-cancelled claim 33.

useful for treating a nervous system disorder that produces one or more neurological events (e.g., such as epilepsy). For example, operating in the manual mode includes receiving a set of information associated with a first treatment therapy configuration from a user and then assessing whether the first set of information is within a range of safety. If the first treatment therapy is determined to be safe in the manual mode, the first treatment therapy can then be automatically initiated in the run mode in response to a neurological event. Support for the amendments to claim 1 can be found throughout Applicant's original Specification, particularly in paragraphs [116]-[120].

In the Final Office Action, the Examiner maintained the rejection of claim 1 over Shaw, stating that Shaw discloses monitoring parameters during treatment and terminating treatment if a parameter deviates from a specific or predetermined value of the parameter.[2] While Applicant appreciates the Examiner's additional comments, Applicant respectfully submits that the Examiner's comments still misinterpret Shaw, at least to the degree that the cited portions of Shaw may apply to the limitations of Applicant's claim 1.

In addition, claim 1 as amended more explicitly provides for a manual mode of operation and a run mode of operation of a medical device system configured to treat a nervous system disorder producing one or more neurological events. As provided, if the first treatment therapy is determined safe in the manual mode of operation, then operating the medical device system in the run mode includes automatically initiating the first treatment therapy to the patient in response to a neurological event. Applicant respectfully submits that Shaw does not disclose these limitations.

While Shaw discusses performing a number of software and hardware safety tests in a disarmed state[3], this disarmed state is not the same as the manual mode provided in claim 1. As just one example, the Shaw does not disclose manually initiating a first treatment therapy to a patient in the disarmed state, but instead discusses a number of hardware self-tests.[4] To the extent stimulation is delivered in the disarmed state, it is not delivered to a patient, but to a dummy load R7 or an internal 10,000 ohm resistor R8.[5]

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[2] Final Office Action, pp. 2-4, sections 3-6; *see* Shaw, col. 29, lines 30-49, and col. 30, lines 20-25 and 35-40, cited in the Final Office Action.
[3] *See, e.g.,* Shaw, col. 26-col. 29, line 29.
[4] *Id.*
[5] *See* Shaw, col. 20, line 65-col. 21, line 29; *see also* FIG. 11B.

In addition, Shaw does not disclose operating in a run mode that automatically initiates a first treatment therapy in response to a neurological event as provided in claim 1. In rejecting now-cancelled claims 17 and 33, "the examiner [considered] the 'run mode' to be the execution of the therapy."[6] However, Shaw is explicitly directed to providing electro-convulsive therapy (ECT), which is used to produce therapeutic seizures.[7] For example, Shaw includes an "armed state," but only begins applying the actual ECT treatment pulse train when it detects that a treatment button has been pressed.[8] While Shaw does include a "Patient Monitoring Section," this portion of Shaw's device is only disclosed as monitoring and digitizing patient signals for display, presumably to monitor the effect of the induced therapeutic seizures.[9] Shaw does not contemplate determining the occurrence of neurological events or taking any action based on a neurological event. Accordingly, Shaw does not automatically initiate a first treatment therapy to the patient in response to a neurological event as claimed.

Applicant thus submits that Shaw does not disclose all of the limitations of independent claim 1 and respectfully requests that the rejection be withdrawn. Applicant also submits that there is no convincing line of reasoning for a finding that it would obvious to modify Shaw to include the undisclosed limitations. Independent claim 25 and new independent claim 40 include several limitations similar to limitations in claim 1, and thus are believed to be patentable at least for the reasons presented above with respect to claim 1. Applicant respectfully requests that the rejection of claim 25 be withdrawn and that claims 25 and 40 be determined allowable.

Dependent Claims

Claims 17 and 33 are cancelled. Claims 2-16, 18-24, and 34-37 depend from claim 1; claims 26-32, 38, and 39 depend from claim 25; and claims 41-46 depend from claim 40, and thus all are believed to be patentable for at least the reasons presented above with respect to their corresponding independent claims, as well as based on several additional limitations in the

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[6] Final Office Action, p. 11, section 31.
[7] *See* Shaw, Abstract, Background and Summary generally, and numerous references to ECT in the Detailed Description.
[8] Shaw, col. 29, lines 37-39.
[9] *See* Shaw, col. 7, lines 47-46 and col. 9 line 37-col. 12; *see also* col. 8, lines 8-14, ("The A-to-D converter 58 digitizes the patient monitoring signals received at inputs 13, 14 and 16 (i.e., EEG, ECG and OMS). This digitized data is then operated on by the DSP 42 to filter out unwanted power line frequency interference by the use of a frequency adaptive finite impulse response (FIR) filter as well as decimate the digitized data for display." Emphasis added.)

dependent claims. Applicant specifically discussed dependent claims 4, 26, and 46 and dependent claims 14, 32, and 44.

As one example, claims 4 and 26 provide that the manual mode comprises receiving an indication from a user as to whether the first treatment therapy is tolerable and executing a corresponding action if it is not tolerable. In the Final Office Action, the Examiner rejected claims 4 and 26 on the basis that Shaw discloses a system that receives "acceptable values" from the user via Shaw's front panel and that the system compares the actual values to the "acceptable values" to determine whether the therapy is tolerable to the patient.[10] Applicant respectfully disagrees with the Examiner's application of Shaw and notes that whether a value is "acceptable" is not the same as "whether the first treatment therapy is tolerable to the patient" as provided in claims 4 and 26. First, Shaw has no teaching that a measure of "acceptance" is necessarily the same as a measure of "tolerance" and the Final Office Action provides no further basis for this conclusion. Second, claims 4 and 26 incorporate the limitations of their independent claims, and thus provide for receiving an indication from the user whether the first treatment therapy, *which has already been manually initiated to the patient*, is tolerable to the patient. The Final Office Action claims that the "acceptable values" come "from the user," but the cited portions of Shaw merely refer to the "parameters of the ECT treatment pulse train" that are "specified by the user via the front panel," and include no reference to a treatment therapy actually received by the patient.[11] New claim 46 depending from claim 40 includes limitations similar to those in claims 4 and 26. Accordingly, Applicant respectfully submits that claims 4, 26, and 46 are patentable over Shaw for at least these additional reasons.

As another example, claims 14 and 32 provide for determining a charge density of an electrode within a configuration of electrodes and rejecting the first set of information and not delivering the first treatment therapy if the charge density is greater than a predetermined threshold. In the Final Office Action, the Examiner cited Shaw's discussion of "patient treatment electrode interface impedance" as determining the charge density.[12] Charge density is clearly different that impedance, and the Examiner has provided no explanation as to how one arrives at the claimed charge density given the measured impedance in Shaw. In addition, when

[10] Final Office Action, p. 5, section 9; Shaw, col. 29, lines 39-42 and col. 30, lines 35-37.
[11] *Id.*
[12] Final Office Action, p. 6, section 15; Shaw, col. 6, lines 48-56.

read in context, Shaw's reference to "patient treatment electrode interface impedance" clearly refers to the "static impedance" or the "dynamic impedance" of the patient, which is measured running from the ECT device through an ECT electrode, through the patient, through the other ECT electrode, and back to the device.[13] This impedance is clearly not the same as the charge density associated with a single electrode and it is unclear at best how one could arrive at the charge density given only this measured impedance. New claim 44 includes limitations similar to those in claims 14 and 32. Accordingly, Applicant respectfully submits that claims 14, 32, and 44 are patentable over Shaw for at least these additional reasons.

Conclusion

Applicants submit that this application is in condition for allowance for at least the reasons presented above. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Michael J. Feller/

Dated: December 2, 2011

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Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

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[13] Shaw, col. 3, lines 7-30; col. 21, lines 50-67.